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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,054	12/03/2001	Andreas Werner Speitling	OSTEONICS 3.0-349	9208

530 7590 10/05/2004

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,054

Applicant(s)

SPEITLING, ANDREAS WERNER

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8,9,11-15,17-19,21-23 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8,9,11-15,17-19,21-23 and 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment of Papers Received: Request for Continued Examination 6/14/04.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 21, 25, 26, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Pratt et al (USPN 4,849,223 hereafter '223). The claims are drawn to a device comprising a body with a sterile surface that is coated with a layer of antibiotic silver ions.

3. The '223 discloses various medical device and implant materials consisting of metallic silver combined with titanium oxide or tantalum oxide (abstract). The antimicrobial coating material comprises silver ions (col. 3, lin. 5- 20, lin. 50 –56; col. 4, lin. 33 – 40; examples). The device also comprises various oxides including tantalum oxide in the coating, as well as hydroxyapatite (col. 3, lin. 1-5). The coating comprises silver ions mixed with tantalum oxide (col. 2, lin. 51 – col. 4, lin., 33). The surface of the device can be smooth dependent upon the intended use of the device (col. 4, lin. 8 – 13). The coating material can also be incorporated into bone cements so that the cement would produce an antimicrobial effect once in the body (*Id.*). The reference also discloses a method for making the device where oxides are incorporated into the coating. These disclosures render the claimed anticipated.

1. Claims 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobson et al (USPN 5,180,585 hereafter '585).

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'585 teaches an antimicrobial coating composition. The composition can comprise silver ions, while the substrate can comprise polyetherether ketone (PEEK) and polylactic acid. The antimicrobial composition can be incorporated or coated onto medical devices for implantation such as sutures, or for dental purposes (col. 4, lin. 18 – 30; col. 5, lin. 33 – 40; col. 9, lin. 12-15; col. 11, lin. 36 – 60). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1,3-6, 8, 9, 11-15, 17-19, 21-23, and 25-30 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Davidson (USPN 5,685,306 hereafter '306), Pratt et al (USPN 4,849,223 hereafter '223) and Jacobson et al (USPN 5,180,585 hereafter '585). The claims are drawn to a medical device comprising a metallic surface and an antimicrobial coating. The coating releases silver ions and can comprise various plastics and ceramics.

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3. '306 discloses medical implants comprising metal and a coating where antimicrobial agents can be applied. The coating comprises ceramic like coatings such as titanium zirconium oxides, and diamond-like carbon (col. 6, lin. 37 – 53; col. 7, lin. 55 – 60). One of the embodiments of the invention of the reference is that of a pacemaker lead, electrical signal transmitter, or a defibrillator. An external source would apply the electrical voltage in the defibrillator and signal transmitter embodiments. In this embodiment electrical voltages would be applied to the surfaces of the device, electrostatically charging the surface of the devices (col. 12, lin. 1 – col. 13, lin. 63). The reference however lacks disclosure of silver zeolites.

4. '223 teaches an antimicrobial coating material for medical devices. The medical devices can have rubber or latex substrates. The antimicrobial coating material comprises silver ions (col. 3, lin. 5- 20, lin. 50 – 56; col. 4, lin. 33 – 40; examples). The device also comprises various oxides including tantalum oxide in the coating. The coating comprises silver ions mixed with tantalum oxide (col. 2, lin. 51 – col. 4, lin., 33). The surface of the device can be smooth dependent upon the intended use of the device (col. 4, lin. 8 – 13). The coating material can also be incorporated into bone cements so that the cement would produce an antimicrobial effect once in the body (*Id.*). The reference also discloses a method for making the device where oxides are incorporated into the coating. The reference also discloses polyvinyl chloride as a possible polymer, to be incorporated into a coating layer, but does not disclose the specific plastics of applicant.

5. '585 teaches an antimicrobial coating composition. The composition can comprise silver ions, while the substrate can comprise polyetherether ketone (PEEK) and polylactides. The antimicrobial composition can be incorporated or coated onto medical devices for implantation

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such as sutures, or for dental purposes (col. 4, lin. 18 – 30; col. 5, lin. 33 – 40; col. 9, lin. 12-15; col. 11, lin. 36 – 60).

6. Regarding the polish of the metal surface, it is the position of the examiner that such a limitations does not impart patentability on the instant claims. The purpose of the polishing step is to sterilize the surface, yet sterilization is an inherent property of all implantable metallic products. Industry standards require that metallic implants are sterilized prior to implantation, and are kept as such until the moment of implantation. The devices disclosed here would have been sterilized by any and all means available to those of ordinary skill. Applicant has yet to provide criticality to polishing over standard sterilization techniques. Until such criticality is established, the claims will remain obviated by the prior art.

7. A skilled artisan would have been motivated to combine the suggestions of the prior art. A skilled artisan would have been motivated to coat the stent of '306 with either the coating compositions of '223 or '585 in order to ward off possible infection during and after implantation. Since a ceramic coating is suggested by '306, '223 would be an obvious choice since hydroxyapatite is disclosed as a possible substrate. Also equally useful as coating substrates are plastics such as polyvinyl chloride, which are useful along with the PEEK of '585. The silver zeolites would have provided improved antimicrobial qualities to the polished metal alloy surface of '306 as well. It would have been obvious to a skilled artisan to coat the device of '306 with either of the coatings taught by '223 or '585, at the time of the invention, with an expected result of a medical device capable of fighting off infection upon implantation or medical use.

Response to Arguments

6. Applicant's arguments filed 6/14/04 have been fully considered but they are not persuasive. Applicant argues that:

- a. The combination of Jacobson, Pratt and Davidson does not obviate the claims since it does not disclose a polishing step
- b. The combination does not involving a coating comprising one of the resorbable polymers.
- c. Davidson does not disclose an implant with an electrical charge on its surface.
- d. Pratt does not disclose resorbable polymers.

7. Regarding argument a., as stated above it is the position of the examiner that such a limitations does not impart patentability on the instant claims. The purpose of the polishing step is to sterilize the surface, yet sterilization is an inherent property of all implantable metallic products. Industry standards require that metallic implants are sterilized prior to implantation, and are kept as such until the moment of implantation. The devices disclosed here would have been sterilized by any and all means available to those of ordinary skill. Applicant has yet to provide criticality to polishing over standard sterilization techniques. Until such criticality is established, the claims will remain obviated by the prior art.

8. Regarding argument b and d, the examiner directs applicant attention to Pratt col. 2, lin. 32-43, and col. 3, lin. 1-4, where the purpose of the invention is presented out to provide an implantable device impregnated or coated with hydrated oxide component, described as

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hydroxyapatite. Applicant describes hydroxyapatite as a resorbable polymer. For this reason the claims remain obviated over the disclosures of Pratt and the other references.

9. Regarding argument c., Davidson describes various embodiments of the invention including lead wires in pacemakers and other leads which carry electrical signals. Applicant is directed to col. 12, lin. 1-29 where the electrical properties of the invention are described. These disclosures render the claims obviated by the prior art.

10. Also in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

All claims have been rejected, no claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

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